

Report of the Care Record Development Board Working Group on the Secondary Uses of Patient Information

Introduction

The NHS CFH Care Record Development Board established a Secondary Uses Working Group to produce a report on Secondary Uses and which was published in August 2007 <http://www.connectingforhealth.nhs.uk/crdb/workstreams>.

PIAG acknowledges the importance of the secondary use of patient information for the effective management of the health service and social care services and for medical research.

The use of patient information, whether for primary or secondary purposes, is governed by the legal, professional and ethical requirements of confidentiality, data protection and the right to privacy. . In order to use information for secondary uses, there must be either:

- a statutory basis for disclosure (which includes powers under S60) OR
- the data must be anonymised prior to disclosure OR
- valid consent for its use in identifiable form sought OR
- Exceptionally, there may be an over-riding public interest justification (see below).

The use of information, therefore, needs to be managed effectively to ensure compliance with requirements.

PIAG would like to emphasise that overall it welcomes the content of this report and the attention it brings to the need for effective management of secondary uses of patient data. This should not be forgotten in considering the comments that follow that may be critical of aspects of the report. PIAG also welcomes the fact that principles outlined in section 4.2 of the report, namely anonymisation, consent or approval under Section 60 (Section 251) fairly reflect the legal position.

PIAG supports the view, in line with what is legally required, that whenever possible anonymised or pseudonymised information should be used for secondary purposes and

that when anonymised or pseudonymised information is not possible, the consent of patients is sought in order to use identifiable information for secondary purposes.

There are however, three key aspects in which PIAG feels the report is problematic, namely:

- 1) The legal basis for disclosure of confidential patient information to ‘Safe Havens’ is neither acknowledged nor addressed by the Report.
- 2) There is a confusion about the requirements for valid consent.
- 3) The report is not always clear in its use of language and fails to distinguish adequately between reference to primary uses of data and when secondary; and when it is discussing data that has been effectively anonymised or pseudonymised and when it is identifiable.

Additionally, PIAG has a number of other comments, which are also included below. Before considering these issues however, we would like to comment on what we understand to be the expectations of the public with respect to the use of their personal health information.

Public Expectations

In section 2.5, reference is made to The Academy of Medical Sciences: *Personal data for public good: using health information in medical research*, which has

“identified a number of the benefits of research. It also expressed concern that overly conservative access controls might hinder research activity and hence reduce such benefits.”

PIAG acknowledges the benefits of research and has throughout its existence worked with the research community to facilitate good quality, ethical research. However, we would question the assertion that access controls are “overly conservative” and out of step with public opinion.

There have been two recent reports of research into public attitudes towards the use of personal information for medical research, one conducted by MORI on behalf of the Medical Research Council (MRC), *The Use of Personal Health Information in Medical Research* and one by the Wellcome Trust, *Public Attitudes to Research Governance: A*

qualitative study in a deliberative context. There is remarkable similarity in the results of these two reports, which indicate:

- a) the public are largely unaware of how their data are used to support medical research
- b) the public are generally supportive of medical research but they expect their consent to be sought for the use of their personal health information for research purposes.

PIAG has supported and continues to support good quality ethical research. PIAG was established, however, on the basis that consent is the starting point for the use of patient identifiable information for any secondary purposes and that Section 60 is only applicable where it can be demonstrated that identifiers are necessary for the activity to be undertaken effectively and where consent is genuinely not practicable.

PIAG recognise the value of good quality, ethical medical research and the need for patient identifiable information for medical research, clinical audit, service evaluation and other medical purposes that may ultimately improve patient care. The recent research reinforces the position adopted by PIAG of the need for greater transparency about the secondary use of patient information, and for communication and engagement with the public about the use of their personal information and what is acceptable in terms of consent to meet both public expectations and legal requirements.

Safe Havens

In section 5.11, the report remarks that Safe Havens (or Honest Brokers) will be established to manage the dissemination of secondary data to users. This is not a new proposal but one that has been around for some time. PIAG recognises that ‘Safe Havens’ can play a valuable role in protecting and ensuring the confidentiality of information, however, PIAG is concerned that the report does not consider the legal basis of disclosure to these Safe Havens. In section 5.1.3, the report indicates a reference to “regulatory framework” for Safe Havens but it is not clear whether this involves the establishment of Safe Havens or the legal power to share information with Safe Havens.

The report does not seem to acknowledge that the establishment of Safe Havens will require transferring patient identifiable information to them. It is this initial transfer of

patient identifiable information that causes PIAG concern. PIAG acknowledges that the use of Safe Havens can protect the confidentiality of patient information, while facilitating the further dissemination of effectively pseudonymised information for secondary uses. However without a clear statutory basis for Safe Havens there may be a situation where the entities designed to protect and promote patient confidentiality may in fact be in breach of the law and principles it was set up to protect.

PIAG would recommend that a statutory basis for the transfer of information to Safe Havens be sought, either through support under Section 60 of the Health and Social Care Act, or by pursuing another legal basis. The key point that needs to be made is that if Safe Havens are providing the necessary assurance to the public as well as to users of information for secondary purposes then it is vital that Safe Havens are not breaching confidentiality themselves.

Consent

In section 5.2.2 of the report it is stated that consent can be assumed for healthcare purposes where the patient has been effectively informed, but that this consent cannot be assumed for the use of information for secondary purposes. PIAG agrees with this position, on the basis that ‘healthcare purposes’ refers to the primary use of data, namely activities very directly supporting the care and treatment of the patient.

This section goes on to say, *“Additional efforts to gain consent are required for these [i.e. secondary] purposes. These can range from a targeted communications exercise to a signed consent form.”*

The difficulty with the phrase ‘additional efforts’ is that it implies consent for secondary uses is not a strict necessity. This may be true in so far as there are exceptions for when consent is not necessary e.g. where there is an over-riding public interest in disclosure or where consent is not practicable, and powers under S60 may be used. However, the use of the phrase ‘additional efforts’ undermines consent as the starting point for the use of identifiable information for secondary purposes. The second sentence goes on to define the form of these additional efforts, i.e. from targeted communications to a signed consent form.

The targeted communications referred to in 5.2.2, are not defined, however, informing patients about the use of their information is only one aspect of the legal requirements

for valid consent. Similarly, a signed consent form can also fail to meet the requirements if it is not accompanied by understanding on the part of the individual.

In order for consent to be legally valid, it must be:

- Informed – patients must be informed at the very least in a broad way
- Understood – patients must have the capacity to understand what is being asked
- Voluntary – patients must not be under undue pressure to consent
- Specific – consent needs to be sufficiently defined

PIAG is in the process of developing guidance on consent.

The report asserts that targeted communications are acceptable to the public and cites two projects. This is not borne out, however, by the two recently published research studies into public attitudes towards the use of personal data for research purposes on behalf of the MRC and the Wellcome Trust and referred to earlier. Both reports indicated that people generally did expect their explicit consent to be sought for the use of identifiable data. It is probably significant that the two projects cited use pseudonymised data rather than identifiable data and why ‘opt out’ may be regarded as acceptable. Such nuances have not been explored in the report and this lack of clarity in the language used can lead to misunderstanding.

A further consideration is that, even if it can be demonstrated that there is broad public support for the use of targeted communications this still places the secondary use of data in a legally anomalous position and open to challenge.

The second part of 5.2.2 states:

“Where the data used is in identifiable format and generally felt to be personally more sensitive, recorded informed consent with positive ‘opt-in’ is more likely to be appropriate than a communications exercise and a negative ‘opt-out’ consent model.”

PIAG’s concern with this sentence, with respect to consent, is the implication that explicit consent is only ‘more likely to be appropriate.’ Whilst, as indicated above, there are exceptions for when consent may not be required, these are derogations from the requirements. ‘More likely to be appropriate’ implies a degree of choice as to whether or not consent is in fact required.

Clarity of language

This report would have benefited from a glossary to explain terms such as healthcare purposes, and the Secondary Uses Service. At times, the report does not make clear when it is referring to healthcare purposes and when to secondary purposes such as medical research; As indicated by the comments on section 5.2.2, this is important as there is a legitimate basis for implying consent for the use of data to support care as part of the consent for treatment and examination, provided adequate information has been given. Another way of considering whether implied consent is reasonable is to consider whether the patient would be surprised by the disclosure of their information, either in terms of purpose, or who has received the information or the extent of the information provided. In contrast, implied consent is not an adequate basis for processing data for secondary purposes, as it does not meet the tests for consent to be valid.

Similarly, the report is not always clear when it is referring to anonymised, pseudonymised or identifiable data. This differentiation is important, as different ‘rules’ apply according to the degree of identifiability of the data.

Guidance

In section 5.2.3 of the report there is a recommendation for clear guidance on the secondary use of identifiable data. The assertion that there is confusion is generally made by those who wish the law were more permissive with respect to processing for secondary uses.

PIAG would argue that clear guidance is provided in the NHS Confidentiality Code of Practice, which states:

“Preventative medicine, medical research, health service management, epidemiology etc are all medical purposes as defined in law. Whilst these uses of information may not be understood by the majority of patients, they are still important and legitimate pursuits for health service staff and organisations. However, the explicit consent of patients must be sought for information about them to be disclosed for these purposes in an identifiable form unless disclosure is exceptionally justified in the public interest or has temporary support in law under section 60 of the Health & Social Care Act 2001.”

PIAG members feel that it would be more appropriate to update the NHS Confidentiality Code of Practice to provide more detailed guidance on the secondary

use of patient information, as opposed to creating separate guidance. It has often been said that this area of law is confusing and reference made to a plethora of apparently conflicting guidance. PIAG would like to challenge this assertion in that the law is clear that personal health information is confidential and that the duty of confidence is owed by the treating clinical care team. To reiterate, in order to use information for secondary uses, there must either be:

- a statutory basis for disclosure (which includes powers under S60) OR
- the data must be anonymised prior to disclosure OR
- valid consent for its use in identifiable form sought OR
- Exceptionally, there may be an over-riding public interest justification.

The responsibility for determining whether there is an over-riding public interest justification resides with the data controller for the information concerned, usually through the clinical team that has legitimate access to the information, not an external body such as a research team. The decision involves balancing the public interest in disclosure with both the individual patient's private interests and the public interest of maintaining public trust in a confidential service. The maintenance of a confidential service is taken very seriously by the courts¹ and therefore the patient / public benefit in favour of disclosure must be substantial in order to warrant a breach of confidence.

Such public interest disclosure decisions must take account of each individual patient's circumstances and be proportionate in line with the requirements of the Human Rights Act. The circumstances where a blanket disclosure of information about a group of individuals may be appropriate will be rare, e.g. extremely serious public health threats and similar. PIAG does not accept that the public interest can therefore have general application to disclosures for secondary uses.

Whilst section 60 powers must be used in the public interest, the threshold is lower than that required to justify breach of confidentiality, as section 60 sets aside the obligation of confidentiality.

Section 60 Support

PIAG supports the view expressed in section 5.3.3 of this report, where it is indicated that there is a need to reduce reliance on special measures for access to patient

¹ Ashworth Hospital Authority v MGN Ltd

identifiable data. PIAG sees one of its key functions as encouraging and facilitating the move to a consent-based culture for use of identifiable data, where the use of patient information for secondary purposes is transparent and where anonymised/pseudonymised information can be used for most routine secondary uses. The NHS is some way from achieving this. PIAG will continue to work with research bodies, the NHS, the Department of Health, patient groups and the National Information Governance Board (NIGB) to achieve this.

PIAG would like to emphasise the point made in the previous section in respect of the limitations of the public interest as a basis for secondary uses of data. Where there is no other statutory basis for disclosure, effectively pseudonymised/anonymised data will not suffice for the purpose, and consent is genuinely not practicable, then applying for Section 60 approval is likely to be the only way that access to patient identifiable information can be legally justified for secondary purposes, although it is recognised that there may be exceptions e.g. the Redfern Enquiry.

Conclusion

PIAG welcomes this report and supports the work to establish the secondary use of information on a secure legal and ethical footing. Whereas PIAG generally supports the views and recommendations of the report, we recommend the following:

- An explicit commitment to obtaining consent for the use of patient identifiable information is the cornerstone of any secondary use principles. Obtaining explicit consent should be the default position in relation to using identifiable patient information for secondary usage.
- That a secure legal basis is established for the transfer of information to Safe Havens either via an application for approval under Section 60 powers or through primary legislation.
- That more detailed guidance on and the requirements for the secondary use of information is incorporated into the NHS Confidentiality Code of Practice.

Appendix 1

The Patient Information Advisory Group

The Patient Information Advisory Group (PIAG) is an independent statutory body set up under Section 60 of the Health and Social Care Act 2001. PIAG's terms of reference are to:

Advise the Secretary of State for Health on use of powers provided by Section 60 of the Health and Social Care Act 2001, and in particular on:

- Applications and proposals for use of these powers;
- Draft regulations made under s60(1) of the Act;

Proposals to vary or revoke such regulations following the Secretary of State's required annual review of existing provisions.

Advise the Secretary of State on key issues, particularly those of national significance, relating to the processing of patient information.

PIAG has been in operation since December 2001 and has considered a wide range of applications for Section 60 support. The role of PIAG is to provide a legal basis for essential NHS activity to continue. It is intended that in time, the National Programme for IT will deliver an effective alternative to identifiable data through the secondary uses service, or will enable the recording and implementation of consent.